In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 23-1192V UNPUBLISHED

DIANE SINCOFF on behalf of her minor child, E.S.,

Chief Special Master Corcoran

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: March 26, 2024

Michelle Greene, The Lanier Law Firm, PLLC, New York, NY, for Petitioner. *Julia M. Collison*, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On July 31, 2023, Diane Sincoff filed a petition for compensation on behalf of her minor child, E.S., under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa—10 through 34 (the "Vaccine Act"). Petitioner alleges that E.S. suffered various injuries from a human papillomavirus ("HPV") vaccination she received on March 15, 2019. ECF No. 1 at 2.

Because the petition was untimely filed, and Petitioner has failed to establish a basis for equitable tolling, this case is **DISMISSED**.

Relevant Factual Background

On March 15, 2019, at the age of thirteen², E.S. went with her mother, Petitioner, to a well-child visit where E.S. received the first dose of the HPV vaccine. Exhibit 5 at 64. At this appointment, the records state that the medical professional "[d]iscussed need for vaccines, reviewed side effects and VIS." *Id.* at 66.

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² Although the petition states that E.S.'s birth month is June, the medical records all indicate that her birth month is February.

On May 21, 2019, E.S. complained to a pediatrician of stomach pain, dizziness, and nausea. ECF No. 1 ¶ 3. At a later appointment on October 8, 2019, E.S. complained of stomachache, nausea, and gas. Id. ¶ 4. E.S. stopped menstruating in March 2020. *Id.* ¶ 5. E.S. was diagnosed the premature ovarian failure on October 20, 2020. *Id.* ¶ 6.

Facially, Petitioner's claim herein was filed over *four* years after the HPV vaccination, which was administered in March 2019, and over *four* years from the time she began manifesting symptoms later in 2019. But Petitioner maintains her delay is excusable. In the response to the order to show cause, Petitioner stated at the time this vaccination occurred, no one discussed the possible adverse side effects of the HPV vaccine, no Vaccine Information Statement (VIS) was provided, and no information was relayed about the Vaccine Program. ECF No. 12 at 2. None of these statements were included in Petitioner's affidavit. Exhibit 1. Petitioner did not learn about the Vaccine Program until April 2023, but then immediately contacted an attorney thereafter. ECF No. 12 at 3. Again, Petitioner did not attest to this statement in her affidavit and only stated it in the response to the order to show cause. Exhibit 1.

Relevant Procedural History

Given that the timeliness of the claim was legitimately called into question merely by the face of the actual Petition, while the case was still in the initial "pre-assignment review" (a process utilized by the Office of Special Masters to assess whether a claim's primary evidentiary documentation has been filed), I ordered Petitioner to show cause why the claim had not been filed outside the Act's 36-month statute of limitations. Sec. 16(a)(2); ECF No. 6.

On October 13, 2023, Petitioner filed a response. ECF No. 12. Petitioner did not dispute the onset of symptoms in 2019, or that the petition was filed in July 2023 (and not sooner than 2022), but instead argued that the limitations period should be equitably tolled. Petitioner asserted that she had diligently pursued a vaccine claim once she became aware of E.S.'s legal rights. Petitioner also made allegations not relevant to a Vaccine Act claim, about the perfidious conduct of the vaccine manufacturer in fraudulently concealing the HPV vaccine's harmful character from the public. ECF No. 12 at 18. Relatedly, Petitioner argued that the failure of a healthcare professional to provide her with a VIS at the time of vaccination can be attributed to the Department of Health and Human Services' failure to systematically ensure that VIS are explained and provided to all vaccine recipients. *Id.* at 4.

On November 13, 2023, Respondent submitted a responsive brief of his own, arguing for dismissal due to untimeliness. ECF No. 15. Respondent maintained that Petitioner in fact had not diligently pursued E.S.'s rights before filing a vaccine claim in

2023 but did not address Petitioner's argument that Petitioner's status as a minor was relevant to the diligence inquiry. Respondent also disputed the veracity of contentions about the manufacturer's conduct, and whether it could in any event constitute an extraordinary circumstance that would serve as a basis for tolling of the statute.

On December 26, 2023, Petitioner filed a reply to Respondent's arguments. ECF No. 17. For the first time, Petitioner raised the argument about the importance of E.S.'s status as a minor when E.S. received the HPV vaccination and that she could not bring a vaccine claim on her own behalf.³

Legal Standards

The Vaccine Act's statute of limitations is thirty-six months. Sec. 16(a)(2). The statute begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis (or even recognized by a claimant as significant). *Id.*; *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act's statute of limitations. See Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1340-41 (Fed. Cir. 2011). However, in keeping with applicable U.S. Supreme Court precedent, equitable tolling of a limitations period is to be permitted "sparingly." Irwin v. Dep't of Veterans Affairs, 498 U.S. 89, 96, (1990). The appropriateness of equitable tolling is ultimately to be determined on a case-by-case basis, without rigid application of any relevant overarching guidelines. Holland v. Florida, 560 U.S. 631, 649–50 (2010); accord Arctic Slope Native Ass'n v. Sebelius, 699 F.3d 1289, 1295 (Fed. Cir. 2012).

Petitioners must prove two elements to establish equitable tolling: (1) that petitioner diligently pursued her rights, and (2) an extraordinary circumstance prevented her from timely filing the claim. *K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1379 (Fed. Cir. 2020) (citing *Menominee Indian Tribe v. United States*, 577 U.S. 250, 255 (2016)).

When first articulating this limited exception to equitable tolling, the Federal Circuit primarily enumerated fraud and duress as a basis for equitable tolling—but not, for example, *lack of awareness* on a petitioner's part that she might have an actionable claim.

Respondent the opportunity to address (and most likely oppose) this argument would not change the result of this decision.

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³ Although the argument about Petitioner's minor status is newly raised in the reply, in many cases with virtually identical legal issues, Respondent has declined to address this argument even when it is raised in the petitioner's initial response to the order to show cause. See Needham v. Sec'y of Health & Hum. Servs., No. 23-630V, 2023 WL 9287882 (Fed. Cl. Spec. Mstr. Dec. 20, 2023); Roman v. Sec'y of Health & Hum. Servs., No. 23-705V, 2024 WL 470570, at *1 (Fed. Cl. Spec. Mstr. Jan. 5, 2024). Allowing

Cloer, 654 F.3d at 1344–45 (noting that tolling of the Vaccine Act's statute of limitations period is not triggered "due to unawareness of a causal link between an injury and administration of a vaccine"). In K.G., 951 F.3d at 1380–82 (Fed. Cir. 2020), the Circuit more explicitly endorsed the proposition that an individual's demonstrated mental incapacity could be a basis for equitable tolling in the Program. For a mentally incapacitated individual, the Circuit instructed that the details of the individual's relationship with her legal guardian would affect whether there was reasonable diligence or extraordinary circumstances. K.G., 951 F.3d at 1382 (Fed. Cir. 2020). More recently, the Circuit concluded that a parent acting as a legal guardian did not have extraordinary circumstances preventing the filing of a petition where the parent: (1) routinely made medical decisions on behalf of the legally incapacitated individual during the relevant time period, (2) had no documented strained relationship with the individual, and (3) had no conflicts of interest dissuading the parent from filing a petition. W.J. v. Sec'y of Health & Hum. Servs., 93 F.4th 1228, 1241 (Fed. Cir. 2024).

<u>Analysis</u>

The untimeliness of this filing is acknowledged by Petitioner, so the only question to be resolved is whether equitable tolling should save the claim. But Petitioner has failed to establish both elements of equitable tolling – diligent pursuit and extraordinary circumstances.

A) Diligent pursuit

Petitioner stated that she diligently began to pursue E.S.'s claim after she learned about the Vaccine Program in April 2023.⁴ Petitioner argues that her diligent pursuit of E.S.'s vaccine claim was impeded by E.S.'s minor status since the vaccine was administered.⁵

These arguments are wholly unpersuasive. It is beyond question that claims asserted in the Vaccine Program are not subject to a "discovery rule," accruing only when a claimant *learns* he or she might possess a cause of action. Rather, the statute of limitations period is triggered by the onset of Petitioner's symptoms – whether or not onset was understood to be the start of the claimed injurious illness or condition. *Cloer v. Sec'y*

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⁴ As noted above, Petitioner has not attested to when she learned about the Vaccine Program or began to diligently pursue E.S.'s vaccine claim. Exhibit 1 (affidavit). Petitioner has only made these statements in the response to the order to show cause. ECF No. 12.

⁵ Although E.S. recently turned eighteen in 2024, E.S. was a minor through all the briefing on the order to show cause and all other relevant periods of the vaccine case. E.S. required her mother to file and prosecute the vaccine claim on her behalf. Thus, no diligent pursuit undertaken by E.S. since she reached the age of majority would affect the analysis of equitable tolling in these circumstances.

of Health & Hum. Servs., 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc). And the failure to be advised of the Vaccine Program or the Act does not support equitable tolling of the statute of limitations period for an otherwise-untimely filed petition. Speights v. Sec'y of Health & Hum. Servs., No. 03-2619V, 2013 WL 5944084, at *13 (Fed. Cl. Spec. Mstr. Oct. 17, 2013). Thus, a petitioner cannot generally shield an untimely claim from dismissal by asserting, even in good faith, that she literally was unaware of her Vaccine Act "rights."

Petitioner attempts to leverage her minor status at the time of vaccination into an exception to the above. The Federal Circuit has conclusively stated that Vaccine Act does <u>not</u> contain a provision for minority tolling and that Congress did <u>not</u> intend to allow minority tolling. *W.J.*, 93 F.4th at 1241. The only savings clause in the Act is for revisions to the Vaccine Injury Table, which allow an otherwise untimely claim for newly added vaccines to be filed. Sec. 16(b). And there is no argument here that a Table claim specifically involving the HPV vaccine was added that would cover Petitioner's delayed filing.⁶

B) Extraordinary Circumstances

Petitioner's arguments about the purported fraudulent conduct of the vaccine's manufacturer, in hiding proof of the vaccine's dangers, deserve even less consideration. ECF No. 12 at 18. As a threshold matter, these contentions are speculative and not evidentiarily-supported. And regardless of their actual truth, the fact remains that the Government has approved the HPV vaccine for administration to minors, rendering it "covered" under the Act. The only issue to be resolved in a Program case is whether (assuming, as here, the claim is not a Table claim) the claim meets the standards for causation – and those standards have nothing to do with a manufacturer's alleged misconduct in preparation or promotion of the underlying vaccine.

These allegations also are not a basis for tolling under the circumstances. Petitioner simply has not shown that contentions of corporate misconduct not specific to, or directed at, her personally could rise to the level of the kind of "fraud" that might excuse failing to file a Program claim in a timely manner. Nor has she persuasively established that the vaccine administrator's "failure to warn," or provide a VIS in 2019, is an extraordinary circumstance. Even assuming the factual accuracy of that allegation,⁷ it

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⁶ In fact, the HPV vaccine was added to the Table in 2007 – *twelve* years before onset is alleged herein to have occurred. 42 C.F.R. § 100.3 (Vaccine Injury Table); National Vaccine Injury Compensation Program: Addition of Meningococcal and Human Papillomavirus (HPV) Vaccines to the Vaccine Injury Table, 72 Fed. Reg. 19937 (Apr. 20, 2007). The Act's lookback provisions have no relevance at all to the timeliness of this claim.

⁷ Petitioner has only stated in the response to the order to show cause, not attested in an affidavit, that she did not receive a VIS or any information about the Vaccine Program during E.S.'s HPV vaccination appointment. ECF No. 12 at 3. But the contemporaneous medical records for the HPV vaccination actually

remains the case (as the Circuit recognized in *Cloer*) that vaccine claims accrue upon onset – and that the failure to be advised of the Vaccine Program does not support equitable tolling. *Cloer*, 654 F.3d at 1340; see also Speights, 2013 WL 5944084, at *13. And arguments about governmental agency knowledge of a failure to warn reflect overheated, almost-conspiratorial allegations that do not come close to excusing the claim's untimely nature.

Finally, Petitioner also asserts that the safety of the HPV vaccine is "heavily disputed and should not be resolved on these papers alone." ECF No. 17 at 7. But this argument willfully ignores the extent to which I have personally ruled in numerous prior cases that medical science does not preponderantly support the contention that the HPV vaccine can cause various autonomic issues. See, e.g., Hughes v. Sec'y of Health & Hum. Servs., No. 16-930V, 2021 WL 839092, at *31 (Fed. Cl. Spec. Mstr. Jan. 4, 2021), mot. for review denied, 154 Fed. Cl. 640 (2021); E.S. v. Sec'y of Health & Hum. Servs., No. 17-480V, 2020 WL 9076620, at *40, 43 (Fed. Cl. Spec. Mstr. Nov. 13, 2020), mot. for review denied, 154 Fed. Cl. 149 (2021); McKown v. Sec'y of Health & Hum. Servs., No. 15-1451V, 2019 WL 4072113, at *44-45 (Fed. Cl. Spec. Mstr. July 15, 2019). Indeed present counsel litigated many of these claims himself. The Act does not require that the same theory rejected so many times before must be relitigated by the Program ad infinitum (especially in the absence of new compelling evidence). Rather, special masters are expressly empowered to rely on their expertise, earned in adjudicating Program cases, in subsequent similar matters. To suggest that they should ignore what they have learned in that process reveals a complete miscomprehension of the Program's underlying goals and purposes.

Conclusion

Thus, Petitioner has failed to establish equitable tolling. This case is dismissed for being untimely filed. The Clerk of Court shall enter judgment accordingly.⁸

IT IS SO ORDERED.

s/Brian H. Corcoran Brian H. Corcoran Chief Special Master

support the conclusion that Petitioner received guidance about the HPV vaccine and a VIS on E.S.'s behalf. Exhibit 5 at 66.

⁸ If Petitioner wishes to bring a civil action, she must file a notice of election rejecting the judgment pursuant to § 21(a) "not later than 90 days after the date of the court's final judgment."